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10/674,205	09/29/2003	Steffen Hansen	6415.200-US	2513

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EXAMINER

RAJ, RAJIV J

ART UNIT	PAPER NUMBER
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4143

NOTIFICATION DATE	DELIVERY MODE
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04/08/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/674,205	Applicant(s) HANSEN ET AL.	
	Examiner RAJIV J. RAJ	Art Unit 4143	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>25 February 2004, 31 March 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Claims

1. This action is in reply to the application filed on 23 September 2003.
2. Claims 1-16 are currently pending and have been examined.

Information Disclosure Statement

3. Information Disclosure Statements filed 25 February 2004 and 31 March 2004 have been considered. Initialed copies of Form 1449 are enclosed herewith.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 15 recites the limitation "*features of the indicating device as defined in any of the previous claims*" on page 6. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner takes the position that Claim 15 should read identically to the limitations of Claim 13.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-5 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellinwood, Jr. (US 4146029) (hereinafter Ellinwood) in view of Neftel (US 5764159) (hereinafter Neftel), in further view of Applicant's Own Admission (hereinafter AOA).

Claim 1

Ellinwood as shown, discloses the following limitations:

- *a reservoir (111) containing an amount of a liquid drug, (see at least Ellinwood, Jr. Fig.12 Item 254)*
- *means (111, 121) for delivering the drug into a body of a user in accordance with a delivery rate value or profile, (see at least Ellinwood, Fig.21 Item 350-362)*
- *second processor means (122) adapted for calculating an estimated time-dependent value based upon received data information and time information from the timer means, and indication means (112) cooperating with the second processor means for indicating a calculated value. (see at least Ellinwood, Fig.15,19)*

Ellinwood does not disclose the following limitations, however Neftel, as shown, does:

- *memory means (124) for storing data information, (see at least Neftel Column:8 Lines:5-13 "means for receiving said sequence of control information from said equipment and for storing at least a portion of said sequence of control information in said memorizing means, whereby at least a portion of the control information relating*

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to each of said equipment in association with information identifying said equipment are memorized, said memorized information including at least the information representative of the operating duration of said equipment;”)

- *timer means (123)*, (see at least Neftel Column:4 Lines:42-44 “The circuits of the control device 10 also include a clock signal or time base 54 which delivers time pulses on an output 54a that are applied to an input 40a”)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine *a reservoir (111) containing an amount of a liquid drug, means (111, 121) for delivering the drug into a body of a user in accordance with a delivery rate value or profile, second processor means (122) adapted for calculating an estimated time-dependent value based upon received data information and time information from the timer means, and indication means (112) cooperating with the second processor means for indicating a calculated value*, taught by Ellinwood, with *the memory means (124) for storing data information and timer means (123)*, taught by Neftel, with the motivation of increasing the efficiency of monitoring and administering medication to patients (see at least Neftel Column:1 Lines:22-26).

Ellinwood/Neftel discloses the previous limitations as shown above. Ellinwood/Neftel does not disclose the following limitations. However AOA, as shown, discloses:

- *first processor means (121), and first transmission means (131) cooperating with the first processor means for transmitting data information to receiving means in the indicating device, the indicating device comprising: (AOA [0009] “the drug infusion device to transmit confirmation or these settings and commands back to the programmer. The return communication link also allows the drug infusion unit to transmit status information back to the programmer”)*
- *first receiving means (132) for receiving data information transmitted from the delivery device, (AOA [0008] “The monitor can be operated in response to*

information received and/or displayed from either the pump or the glucose sensor to thereby control pump operation through the use of radio telemetry signals.”)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations, taught by Ellinwood/Neftel, with the *first processor means (121)*, and *first transmission means (131) cooperating with the first processor means for transmitting data information to receiving means in the indicating device, the indicating device comprising and first receiving means (132) for receiving data information transmitted from the delivery device*, as disclosed by AOA, with the motivation of providing a more effective and efficient process for administering and monitoring a patient's medication (see at least AOA [0002]).

Claim 2

The combination of Ellinwood/Neftel/AOA discloses the previous limitations as shown above.

Ellinwood further discloses the following limitation:

- *calculating a time-dependent estimate for the drug on the basis of the current amount, the time information, and a delivery rate value or profile* (see at least Ellinwood, Jr. Fig.15,19)

Ellinwood discloses the previous limitations as shown above. Ellinwood does not disclose the following limitations. However Neftel, as shown, discloses:

- *storing data information representing the current amount of a drug*, (see at least Neftel Column:8 Lines:5-13)
- *stored in the memory means*. (see at least Neftel Column:8 Lines:5-13)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations, taught by Ellinwood/Neftel/AOA, with the *storing data information representing the current amount of a drug* and *stored in the memory means*, taught by Neftel, with the motivation of increasing the efficiency of monitoring and administering medication to patients (see at least Neftel Column:1 Lines:22-26).

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The combination of disclose the previous limitations as shown above. Ellinwood/Neftel does not disclose the following limitations. However AOA, as shown, discloses:

- *transmitting data information representing a current amount of drug contained in the reservoir*, (AOA [0008] “The glucose sensor is associated with a telemetry unit transmitting glucose measurement signal information by means of radio telemetry to the infusion pump for closed loop operation thereof.”)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations, taught by Ellinwood/Neftel/AOA, with the *transmitting data information representing a current amount of drug contained in the reservoir*, as disclosed by AOA, with the motivation of providing a more effective and efficient process for administering and monitoring a patient’s medication (see at least AOA [0002]).

Claim 3

The combination of Ellinwood/Neftel/AOA discloses the previous limitations as shown above.

Ellinwood further discloses the following limitation:

- *calculating a time-dependent estimate for the drug on the basis of the current amount, the time information, and the delivery rate value or profile* (see at least Ellinwood, Jr. Fig.15,19)

Ellinwood discloses the previous limitations as shown above. Ellinwood does not disclose the following limitations. However Neftel, as shown, discloses:

- *storing the received data information*, (see at least Neftel Column:8 Lines:5-13)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations, taught by Ellinwood/Neftel/AOA, with *storing the received data information*, taught by Neftel, with the motivation of increasing the efficiency of monitoring and administering medication to patients (see at least Neftel Column:1 Lines:22-26).

The combination of disclose the previous limitations as shown above. Ellinwood/Neftel does not disclose the following limitations. However AOA, as shown, discloses:

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- *transmitting data information representing an initial amount of drug contained in the reservoir, a current amount of the drug and a delivery rate value or profile for the drug, (AOA [0008] & [0009] “The glucose sensor is associated with a telemetry unit transmitting glucose measurement signal information by means of radio telemetry to the infusion pump for closed loop operation thereof” and “allows the drug infusion unit to transmit status information back to the programmer”)*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations, taught by Ellinwood/Neftel/AOA, with *transmitting data information representing an initial amount of drug contained in the reservoir, a current amount of the drug and a delivery rate value or profile for the drug*, as disclosed by AOA, with the motivation of providing a more effective and efficient process for administering and monitoring a patient's medication (see at least AOA [0002]).

Claim 4

The combination of Ellinwood/Neftel/AOA discloses the previous limitations as shown above.

Ellinwood further discloses the following limitation:

- *the amount of drug delivered, the amount of drug remaining in the reservoir. (see at least Ellinwood, Jr. Fig.22 Items:150-155, 370)*

Claim 5

The combination of Ellinwood/Neftel/AOA disclose the previous limitations as shown above.

Neftel further discloses the following limitation:

- *determining the time lapsed since the last data information was received, and indicating information indicative of the time lapsed. (see at least Neftel Column:1 Lines:57-60 “means for generating time information; (14) means for initializing the time information relative to said equipment effectively being controlled, thereby obtaining elapsed time information;”)*

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It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations, taught by Ellinwood/Neftel/AOA, with *determining the time lapsed since the last data information was received, and indicating information indicative of the time lapsed*, taught by Neftel, with the motivation of increasing the efficiency of monitoring and administering medication to patients (see at least Neftel Column:1 Lines:22-26).

Claim 10

The combination of Ellinwood/Neftel/AOA disclose the previous limitations as shown above.

Neftel further discloses the following limitation:

- *the first processor means is adapted to transmit ID data information indicative of a unique delivery device*, (see at least Neftel Column:5 Lines:27-30 “the memory circuit 34 includes an instruction for identifying the control device and the information sequence transmitted by the portable device 10 also includes identification information.”)
- *the second processor means being adapted for checking the ID data information before storing updated data information in the memory means*. (see at least Neftel Column:5 Lines:30-34 “The processor circuit 32 compares the two items of identification information and the instructions for controlling operation of the equipment are not performed unless the two items of identification information match.”)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations, taught by Ellinwood/Neftel/AOA, with *the first processor means is adapted to transmit ID data information indicative of a unique delivery device*, and *the second processor means being adapted for checking the ID data information before storing updated data information in the memory means*, taught by Neftel, with the motivation of increasing the efficiency of monitoring and administering medication to patients (see at least Neftel Column:1 Lines:22-26).

Claim 11

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The combination of Ellinwood/Neftel/AOA disclose the previous limitations as shown above.

Neftel further discloses the following limitation:

- *data information stored in the memory means can be indicated by the indication means.* (see at least Neftel Column:8 Lines:5-13 & Fig.3 Items:16, 42)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations, taught by Ellinwood/Neftel/AOA, with *data information stored in the memory means can be indicated by the indication means*, taught by Neftel, with the motivation of increasing the efficiency of monitoring and administering medication to patients (see at least Neftel Column:1 Lines:22-26).

Claim 12

The combination of Ellinwood/Neftel/AOA disclose the previous limitations as shown above.

AOA further discloses the following limitation:

- *the indication means is in the form of a display (320) allowing continuous display of an estimated value.* (AOA [0007] "The remote commander comprises a display allowing the user to visually confirm the values entered into the remote commander.")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations, taught by Ellinwood/Neftel/AOA, with *the indication means is in the form of a display (320) allowing continuous display of an estimated value*, taught by Neftel, with the motivation of increasing the efficiency of monitoring and administering medication to patients (see at least Neftel Column:1 Lines:22-26).

Claim 13

Ellinwood as shown, discloses the following limitations:

- *processor means, where the processor means is adapted for calculating an estimated time-dependent value based upon received data information and time*

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information received from the timer means, and indication means for indicating a calculated value. (see at least Ellinwood, Jr. Fig.15,19)

Ellinwood does not disclose the following limitations, however Neftel, as shown, does:

- *memory means for storing data information,* (see at least Neftel Column:8 Lines:5-13)
- *timer means,* (see at least Neftel Column:4 Lines:42-44)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations, taught by Ellinwood/Neftel/AOA, with *memory means for storing data information* and *timer means*, taught by Neftel, with the motivation of increasing the efficiency of monitoring and administering medication to patients (see at least Neftel Column:1 Lines:22-26).

Ellinwood/Neftel disclose the previous limitations as shown above. Ellinwood/Neftel do not disclose the following limitations. However AOA, as shown, discloses:

- *receiving means for receiving a signal containing data information,* (AOA [0008] “information received and/or displayed from either the pump or the glucose sensor to thereby control pump operation through the use of radio telemetry signals.”)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations, taught by Ellinwood/Neftel/AOA, with *receiving means for receiving a signal containing data information*, as disclosed by AOA, with the motivation of providing a more effective and efficient process for administering and monitoring a patient's medication (see at least AOA [0002]).

Claim 14

The combination of Ellinwood/Neftel/AOA disclose the limitations of Claim 13.

AOA further discloses the following limitation:

- *receiving means is adapted for receiving a remotely generated signal containing data information,* (AOA [0008] “information received and/or displayed from either the pump or the glucose sensor to thereby control pump operation through the use of radio telemetry signals.”)

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It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations, taught by Ellinwood/Neftel/AOA, with *receiving means is adapted for receiving a remotely generated signal containing data information*, as disclosed by AOA, with the motivation of providing a more effective and efficient process for administering and monitoring a patient's medication (see at least AOA [0002]).

Claim 15

The combination of Ellinwood/Neftel/AOA disclose the limitations of Claim 13. With regard to the limitation of:

- *features of the indicating device as defined in any of the previous claims*

Please refer to the rejection of Claim 13.

Claim 16

The combination of Ellinwood/Neftel/AOA disclose the limitations of Claim 13.

Ellinwood further discloses the following limitation:

- *a reservoir containing an amount of a liquid drug*, (see at least Ellinwood, Jr. Fig.12 Item 254)
- *means for delivering the drug into a body of a user in accordance with a delivery rate value or profile*, (see at least Ellinwood, Jr. Fig.21 Item 350-362)

Ellinwood does not disclose the following limitations, however AOA, as shown, does:

- *means for providing data information to the indicating device, the means being readable or actuatable by the indicating device*. (AOA [0008] "The glucose measurements may alternately be transmitted to an externally located monitor")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations, taught by Ellinwood/Neftel/AOA, *means for providing data information to the indicating device, the means being readable or actuatable by the indicating device*, as disclosed by AOA, with the motivation of providing a more effective and efficient process for administering and monitoring a patient's medication (see at least AOA [0002]).

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10. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over AOA in view of Neftel in further view of Ellinwood.

Claim 6

AOA as shown, discloses the following limitations:

- *second receiving means (151) for receiving commands transmitted from the indicator device,* (AOA [0008]), “The glucose sensor is associated with a telemetry unit transmitting glucose measurement signal information by means of radio telemetry to the infusion pump for closed loop operation thereof” and “allows the drug infusion unit to transmit status information back to the programmer”)
- *second transmission means (152) for transmitting commands to the delivery device,* (AOA [0009] “transmit flow rate settings and other commands to the drug infusion device, and also allows the drug infusion device to transmit confirmation or these settings and commands back to the programmer”)

AOA does not disclose the following limitations, however Neftel, as shown, does:

- *the second transmission means being controllable by the user and/or by the second processor means.* (see at least Neftel Column:4 Lines:29 “The microprocessor 40 can receive instructions issued by the user”)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations, taught by AOA/Neftel/Ellinwood, with *the second transmission means being controllable by the user and/or by the second processor means*, taught by Neftel, with the motivation of increasing the efficiency of monitoring and administering medication to patients (see at least Neftel Column:1 Lines:22-26).

Claim 7

The combination of AOA/Neftel disclose the previous limitations as Claim 6.

AOA further discloses the following limitation:

- *the first transmission means is operated in response to commands received from the second transmission means.* (AOA [0008] “The glucose sensor is associated with a

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telemetry unit transmitting glucose measurement signal information by means of radio telemetry to the infusion pump for closed loop operation thereof.”)

11. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over AOA in view of Neftel in further view of Ellinwood.

Claim 8

The combination of AOA/Neftel disclose the previous limitations as shown above.

AOA further discloses the following limitation:

- *the first transmission means is operated in response to commands received from the second transmission means.* (AOA [0008] “The glucose sensor is associated with a telemetry unit transmitting glucose measurement signal information by means of radio telemetry to the infusion pump for closed loop operation thereof.”)

AOA does not disclose the following limitations, however Ellinwood, as shown, does:

- *operated by the second processor means at predetermined intervals.* (see at least Ellinwood Column:6 Lines:17-20 “depending on whether the sensed data is or is not indicative of a need for medication, the dispenser control 31 will operate in a manner to cause the dispenser 32 to either remain off or to be operated to dispense some predetermined amount of medication from the storage 29 according to the patient's needs”)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations, taught by AOA/Neftel, with *operated by the second processor means at predetermined intervals*, as disclosed by Ellinwood, with the motivation of providing a more effective and efficient process for administering and monitoring a patient's medication (see at least Ellinwood Column:1 Lines:18-21).

Claim 9

The combination of AOA/Neftel disclose the previous limitations as shown above.

AOA further discloses the following limitation:

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- *means (312, 313) for inputting a bolus command*, (AOA [0007] “system in which a remote commander can be used to selectively activate a desired function in an external infusion pump device, e.g. delivery of a bolus, selecting a profile for the bolus, or selecting a basal infusion rate.”)
- *wherein the delivery device is adapted for delivering a bolus in response to the bolus command and* (see at least AOA [0007] “The control device may be used to select a desired basal rate, to select a given infusion schedule or to command the infusion of a bolus having a desired size and infusion profile.”)
- *for transmitting data information to the indicating device confirming that the bolus command has been received, and* (AOA [0009] “allows the programmer to transmit flow rate settings and other commands to the drug infusion device, and also allows the drug infusion device to transmit confirmation or these settings and commands back to the programmer”)
- *the second processor means being adapted for transmitting the bolus command to the delivery device*, (AOA [0007]) (AOA [0009])

AOA does not disclose the following limitations, however Ellinwood, as shown, does:

- *wherein the second processor means is adapted for calculating the time-dependent estimate for the drug utilizing the additional data information for the bolus command* (see at least Ellinwood, Jr. Fig.15,19)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations, taught by AOA/Neftel, with *wherein the second processor means is adapted for calculating the time-dependent estimate for the drug utilizing the additional data information for the bolus command*, as disclosed by Ellinwood, with the motivation of providing a more effective and efficient process for administering and monitoring a patient's medication (see at least Ellinwood Column:1 Lines:18-21).

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Conclusion

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Rajiv J. Raj** whose telephone number is **571-270-3930**. The Examiner can normally be reached on Monday-Friday, 7:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **James A. Reagan** can be reached at **571.272.6710**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair> <<http://pair-direct.uspto.gov>>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

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Date: 03/25/08

/Rajiv J Raj/ Patent Examiner Art Unit 4143

/James A. Reagan/Supervisory Patent Examiner, Art Unit 4143